

### **DETAILED ACTION**

1. This Office action is in response to the amendment filed on 12/29/09.

#### ***Response to Amendment***

2. According to the amendment, claim 5 has been canceled and claims 1-3, 8, and 63 have been amended. Accordingly, claims 1-4, 6-10, 32-41, 54, 55, 59, 60, 63, 65 and 66 are pending in this present application and claims 1-4, 6-10, 63, 65 and 66 are presented for examination.

#### ***Response to Arguments***

3. As to point I., pages 7-8 in the remarks, Claim 5 has been canceled, therefore, the objection and the rejection under 35 USC 112, second paragraph have been withdrawn. Claims 1, 3, and 63 have been amended to overcome the rejection under 35 USC 112, first paragraph, therefore, the rejection has been withdrawn.
4. As to point II., pages 8-13 in the remarks, Applicant's arguments have been fully considered and they are persuasive, therefore, the rejection have been withdrawn. However, upon further search and consideration, claims 1-4, 6-10, 63, 65 and 66 are rejected in view of new ground of rejection.

#### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
7. **Claims 1-2, 63, 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrlich (U.S. 2,801,633) in view of Humphrey (U.S. 5,607,401).**
8. Referring to **claims 1, 2, 63, 65 and 66**, Ehrlich discloses (Fig. 8) a unitary hollow lancet 23 having a first end (24) and a second end (opposite of 24), wherein the first end includes first and second sharpened tips 24s, the first and second sharpened tips spaced directly opposite each other and extending parallel to a longitudinal axis of the hollow lancet 23. Ehrlich discloses the lancet further include a portion for user to hold (Col. 6: 55-60) and the point is designed to give a length of 1 to 3 mm, which is the penetration depth that provide the most abundant capillaries (Col. 2:7-10 and Col. 3:10-15). Ehrlich also discloses providing a gauge for the depth of penetration of the point and providing stop elements limiting the depth of penetration of the point to the region of the most abundant blood supply beneath skin (Col. 2: 11-15). Ehrlich discloses the invention substantially as claimed except for disclosing the lancet is a seamless member. However,

Humphrey discloses seamless hypodermic needle and lancet that are formed of polymeric material provide the advantage of the needle and lancet can be made in smaller diameter, resulting in less pain and less costly to manufacture (Col. 2: 35-36 and 49-51). Humphrey also discloses the geometry point of the needle and lancet can be either: flat, oblique, compound, double points or conical (Col. 6: 62-65 and Figs. 10-19). It would have been obvious to one of ordinary skill in the art to use the method of making the needle and lancet as taught by Humphrey to make the lancet as taught by Ehrlich in order to gain the advantage as taught by Humphrey.

9. With respect to the limitation of "first and second ground surfaces" in **claims 1 and 63**, is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S. P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3. Figure 7 of Ayres' drawings (Ayres, U.S. 3,906,932) show the tip of the needle point is formed by grinding process. Examiner contends that in the art of needle and lancet making using grinding process to make the tip geometry is old and well known in the art. It would have

been obvious to use grinding process to produce the tip geometry as shown in Figure 7 as disclosed by Ayres to make the needle point as disclosed by Ehrlich because it has been held that using known manufacturing method to facilitate ease of manufacturing an article is old and well known in the art.

10. **Claims 3, 4, and 6-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ehrlich (U.S. 2,801,633) in view of Ayres (U.S. 3,906,932).**

Referring to **claims 3 and 4**, Ehrlich discloses (Fig. 8) a unitary hollow lancet 23 having a first end (24) and a second end (opposite of 24), wherein the first end includes first and second sharpened tips 24s, the first and second sharpened tips spaced directly opposite each other and extending parallel to a longitudinal axis of the hollow lancet 23. Ehrlich discloses the lancet having a portion for the user to hold (Col. 6: 55-60) and the point is designed to give a length of 1 to 3 mm, which is the penetration depth that provide the most abundant capillaries (Col. 2:7-10 and Col. 3:10-15). Ehrlich discloses the invention substantially as claimed except for disclosing the lancet is a seamless member. However, Ayres discloses using a unitary seamless cylindrical tube and grinding process to make a needle and needle point similar as taught by Ehrlich (Col. 2: 48-55 and Figs. 1, 3 & 7 and). It would have been obvious to one of ordinary skill in the art to incorporate the method of making the point geometry as disclosed by Ayres to make the geometry point of lancet as disclosed by Ehrlich in order to gain the advantage of eliminating the rolling and stamping processes. Further, it would have been obvious to use grinding process to produce the tip geometry as shown

in Figure 7 as disclosed by Ayres to make the needle point as disclosed by Ehrlich because it has been held that using known manufacturing method to facilitate ease of manufacturing an article is old and well known in the art.

With respect to the limitation of "first and second ground surfaces" in **claim 3**, is product-by-process claims. Here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q. 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.

With respect to the lancet is made from stainless steel. However, stainless less steel is old and well known in the art for exhibiting excellent mechanical strength, biocompatibility and super corrosion resistant. It would have been obvious to one of ordinary skill in the art to make the needle of Ehrlich/Ayres from stainless steel material so that it too would have the same advantage. Further, It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the needle of Ehrlich/Ayres made from stainless steel, since it has been held to be within the general skill of a worker in the art to select a

known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

11. Referring to **claims 6-10**, Ayres discloses (Fig. 7) the first ground surface and second ground surface is a single angle ground surface and each of the ground surface extends from the horizontal plane at an acute angle relative to the longitudinal axis. Figure 7 shows the first and second surfaces mirror one another about the horizontal plane and each surface extends approximately 180 degrees about the longitudinal axis.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on 9:00 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Tuan V Nguyen/  
Examiner, Art Unit 3731

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Supervisory Patent Examiner, Art Unit 3731  
4/8/10